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Reverse Payment Claims Authorized Under State Law: Five Lessons from California's *In re Cipro* Decision

Darryl Wade Anderson · Tuesday, August 11th, 2015

Opening a new front in litigation over so-called reverse payment pharmaceutical patent infringement settlements, the California Supreme Court recently held that private parties can challenge these settlements under its state antitrust law, the Cartwright Act.^[1] The court relied heavily on the U.S. Supreme Court's decision interpreting federal antitrust law in *F.T.C. v. Actavis, Inc.*,^[2] importing many of the same federal standards into California law. In so doing, the *Cipro* court elaborated on these standards beyond the relatively narrow holding of *Actavis* and rejected the contention that state law claims were preempted by federal patent law. The decision has important lessons for pharmaceutical companies facing reverse payment litigation in California and beyond.

Background

The *Cipro* decision arose out of a settlement of a lawsuit brought by a branded pharmaceutical company against a generic manufacturer, alleging that the generic's proposed version of the drug Cipro infringed the branded company's patents. The parties' 1997 settlement agreement provided, among other things, that the generic company would not market its version of Cipro until the branded company's patent expired in 2003, and in exchange, the branded company agreed to payments to the generic manufacturer that ultimately totaled approximately \$398 million. Antitrust litigation by consumers of Cipro followed in a variety of state and federal forums; the *Cipro* decision stemmed from several California indirect purchaser class actions brought against both the branded and generic manufacturers.

The Core Holding

Following *Actavis*, the California Supreme Court rejected (under state law) the "scope of the patent" test, by which settlements would be insulated from antitrust challenge as long as they did not delay entry of the generic any longer than the life of the patent at issue.^[3] Instead, again as in *Actavis*, the court adopted a rule of reason analysis for reverse payment settlements, rejecting the argument that they should be treated as *per se* unlawful.^[4]

But, while *Actavis* left “to the lower courts the structuring of the present rule-of-reason antitrust litigation,”^[5] *Cipro* set forth a burden-shifting structure for applying the rule of reason under California law.

To establish a *prima facie* case, *Cipro* held, the plaintiff must show that: “(1) the settlement includes a limit on the settling generic challenger’s entry into the market; (2) the settlement includes cash or equivalent financial consideration flowing from the brand to the generic challenger; and the consideration exceeds (3) the value of goods and services *other* than any delay in market entry provided by the generic challenger to the brand, as well as (4) the brand’s expected remaining litigation costs absent settlement.”^[6]

Although the ultimate burden of proof remains on the plaintiff at all times, the third and fourth elements are presumptively satisfied unless the defendants provide evidence on those issues. “[O]nce a plaintiff has shown an agreement involving a reverse payment and delay [the first two elements], the defendants have the burden of coming forward with evidence of litigation costs and the value of collateral products and services” because, in the court’s view, the defendants generally are more likely to have this information.^[7]

The court noted, however, that when the branded manufacturer was not involved in the antitrust litigation (as was the case in *Cipro*, because the branded manufacturer previously had settled), the generic would not likely have any enhanced knowledge of the branded company’s expected patent litigation costs, so that “the burden of production on this point would remain with plaintiffs.”^[8]

This four-pronged showing by plaintiffs is “sufficient to make out a *prima facie* case that the settlement is anticompetitive,”^[9] and “suffice[s], without more, to raise a presumption of the patentee’s market power.”^[10] As a consequence, the settlement will be deemed invalid under California antitrust law unless the defendants can “offer legitimate justifications and come forward with evidence that the challenged settlement is in fact procompetitive.”^[11]

The *Cipro* court provides scant guidance as to what types of justifications might be deemed sufficient under California law to justify a reverse payment settlement, but it does suggest that certain possible justifications are inadequate. Most prominently, the court suggests that evidence that the patent was in fact valid is not dispositive, stating that “later evidence of validity will not automatically demonstrate an agreement was procompetitive.”^[12] If a settlement agreement delays generic entry beyond the reasonably expected entry date based on an assessment of the strength of the patent at the time of settlement, the settlement may be deemed anticompetitive, *even if* it is later determined that the patent was valid.

As the *Cipro* court put it, “[a]ntitrust law condemns the purchase of freedom from competition; what matters is whether a settlement postpones market entry beyond the average point that would have been expected at the time in the absence of

agreement.”^[13]

Ultimately, if a defendant is able to adduce procompetitive justifications supporting the settlement, the plaintiff must “dispel these justifications” to meet its “burden of demonstrating the settlement agreement is an unreasonable restraint of trade under the Cartwright Act.”^[14]

Rejection of Preemption Arguments

In adopting and extending the *Actavis* rationale to state law claims, the California Supreme Court rebuffed arguments that the exclusively federal jurisdiction over patents limited state law claims. The court acknowledged that “[t]he United States Supreme Court is the final arbiter of questions of patent law and the extent to which interpretations of antitrust law—whether state or federal—must accommodate patent law’s requirements.”^[15] The court explained, however, that “the lesson of *Actavis* is that nothing in the patent laws or the Hatch-Waxman Act dictates” any “special rule” protecting patents.^[16]

Thus, the court concluded it was free to adopt rules under state antitrust law that extended or even diverged from federal antitrust law.^[17]

Five Key Takeaways

The *Cipro* decision has important consequences for both branded and generic pharmaceutical companies, in California specifically, and also in other states. Below are five key takeaways from *Cipro* with respect to litigating reverse payment claims in California and in other states in the future.

1. Likely Increase in State Antitrust Claims

The decision opens the door to more claims by a broader array of potential plaintiffs. One can expect plaintiffs to press other states to similarly recognize challenges to reverse payment settlements under their antitrust laws. Moreover, the availability of state antitrust claims provides a vehicle for indirect purchasers (who are barred from asserting federal antitrust claims) to pursue these claims.

2. Limited Ability to Assert Patent Rights As a Defense to California-Based Claims

The court went well beyond the holding in *Actavis* in diminishing the importance of the branded pharmaceutical’s patents. The U.S. Supreme Court suggested that its rule of reason analysis would give patents a wide berth; it would “normally not [be] necessary to litigate patent validity to answer the antitrust question” because “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.”^[18]

Cipro arguably goes a step further, and uncouples the existence of an “unexplained large” payment from the need to consider the validity of the patent; the court held

that “[a]greements must be assessed as of the time they are made” such that “later evidence of validity will not automatically demonstrate an agreement was procompetitive.”^[19]

Plaintiffs will no doubt argue that this rule should be interpreted broadly to mean that defendants can be held liable for an antitrust violation, even if the patents at issue were conclusively adjudicated to have been valid all along. Defendants, on the other hand, will emphasize that just because patent validity does not “automatically” mean the agreement was procompetitive that should not be interpreted to preclude evidence of patent validity in assessing the competitive effects of the challenged agreement.

3. Non-Cash Payments Can Form the Basis for a California-Based Claim

The court embraced, under California law, an expansive reading of what constitutes a “reverse payment.” In *Actavis*, the U.S. Supreme Court emphasized the payment of money, and some subsequent decisions have held that an antitrust challenge can only be brought when a cash payment is part of the settlement.^[20] In *Cipro*, the California Supreme Court defined a reverse payment as “financial consideration flowing from the brand to the generic challenger” and emphasized that “courts considering Cartwright Act claims should not let creative variations in the form of consideration result in the purchase of freedom from competition escaping detection.”^[21]

4. California Skepticism About Reverse Payment Settlements

Perhaps most troubling for defendants, the court expressed considerable skepticism about reverse payment settlements generally. The court stated that “[c]onsiderable caution is in order in evaluating settlements that include side agreements for generic products or services.”^[22] Indeed, according to the court, “[a] side agreement involving difficult-to-value assets might conceivably be added to a patent settlement to provide cover for the purchase of additional freedom from competition.”^[23]

The court went so far as to hold open the possibility of revisiting the applicability of the *per se* rule to reverse payment settlements in the future. In adopting the rule of reason standard, the court stated that “[w]e are unwilling to declare every settlement payment of a certain size illegal. Like the United States Supreme Court, we cannot say with reasonable certainty—*yet*—that we have posited every possible justification that might render a particular reverse payment settlement procompetitive.”^[24]

5. Grounds for Defending Reverse Payment Settlements in California and Other States Remain

Finally, it should not be overlooked that defendants continue to retain significant defenses to these claims, both in California and in other states where plaintiffs may try to invoke other state antitrust laws. Notwithstanding the overall tone of the *Cipro* opinion, the court acknowledged that “[p]arties can still use financial considerations to bridge small gaps arising from differing subjective perceptions of their probabilities of success in litigation.”^[25]

Moreover, by staking out an interpretation of state antitrust law that goes beyond *Actavis* in minimizing the importance of potentially valid patents, the decision may be superseded by federal patent law developments that contradict the California Supreme Court's understanding of the requirements of patent law.

Other states may reach the reasonable conclusion that their antitrust laws should not be so broadly interpreted, to avoid potential conflicts with federal law down the road.

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1. *In re Cipro Cases I & II*, 348 P.3d 845, 61 Cal. 4th 116 (Cal. 2015).
2. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).
3. *Cipro*, 61 Cal. 4th at 139.
4. *Id.* at 158.
5. *Actavis*, 133 S. Ct. at 2238.
6. *Cipro*, 61 Cal. 4th at 151 (emphasis in original).
7. *Id.* at 153.
8. *Id.* at 153 n. 13.
9. *Id.* at 154.
10. *Id.* at 157.
11. *Id.*
12. *Id.* at 158.
13. *Id.* at 158-59.
14. *Id.* at 160.

15. *Id.* at 142.

16. *Id.* at 161.

17. *See id.* at 161-62.

18. *Actavis*, 133 S. Ct. at 2336.

19. *Cipro*, 61 Cal. 4th at 158.

20. *See, e.g., In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 192-93 (D. R. I. 2014) (“Reading *Actavis*, this Court cannot help but find that it applies solely to monetary settlements.”), appeal docketed, No. 14-2071 (1st Cir. Oct 14, 2014). *But see, e.g., King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, No. 14-1243, — F.3d —, 2015 WL 3967112, at *10 (3d Cir. June 26, 2015) (“We do not believe *Actavis*’s holding can be limited to reverse payments of cash.”).

21. *Cipro*, 61 Cal. 4th at 151 & n. 11.

22. *Id.* at 152.

23. *Id.*

24. *Id.* at 158 (emphasis added); *see also id.* at 162.

25. *Id.* at 156.

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